REMARKS/ARGUMENTS

A. Amendments and Status of the Claims

By the present amendment, claims 67, 74-81, 84-91, 95-111, and 114-145 are pending in this application, of which claims 95-110 and 130-144 have been allowed. Claims 67, 91, 95, 111, 129, and 130 are amended herein to more particularly define the invention and to claim it with greater specificity. Basis for these amendments my be found in the specification and claims as originally filed. No new matter has been added.

The Applicants would like to thank Examiner Spivack and her supervisor for granting a telephone interview on January 6, 2009, during which the Office Action and the technical aspects of the Applicants' invention were discussed. The Applicants would like to put on record the fact that a tentative agreement was reached that the obviousness rejections over Nagley in view of Page may be overcome if the language "comprising" in claims 67, 91, and 95 is replaced with the "consisting of" clause. The Applicants further confirm that no agreement was reached as to the rejections under 35 U.S.C. § 112, first paragraph, as discussed in detail below.

Finally, the Applicants acknowledge the Examiner's request to provide the information regarding certain von Borstel patents that she previously reviewed but which are not included in any previously filed Information Disclosure Statement. In response, a thorough and careful search of all the pertinent records has been made, but no additional von Borstel patents have been found.

A petition for a three-month extension of time under 37 CFR § 1.136(a) and requisite fee accompanies this response.

A Request for Continued Examination (RCE) under 37 CFR § 1.114 accompanies this response.

B. Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 67, 74-81, 84-91, 111, and 114-129 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement for introducing new matter (see, page 2, third paragraph of the Office Action). The rejection is respectfully traversed.

The Examiner has stated that the recitation of the primary and secondary disorders allegedly introduces new matter. As a preliminary matter, the Applicants would like to respectfully remind that the limitations reciting primary and secondary disorders were added in response to the Examiner's explicit requirement to specify a possibility that the recited mitochondrial disorders may be either primary or secondary. In a previous Office Action mailed May 12, 2008, the Examiner based her 35 U.S.C. § 112, second paragraph, rejection based on her observation that the claims are silent with regard to such a possibility.

Substantively, it is submitted that in fact the recitation of either type of disorder introduces no new matter. More specifically, the limitation "a primary disorder comprising at least one mutation in mitochondrial or nuclear DNA" finds ample support in the original application as filed. See, the original claim 6 and page 1, lines 15-16 of the application. Thus, there is explicit support for the limitation "a primary disorder comprising at least one mutation in mitochondrial or nuclear DNA."

Further, the limitation "a secondary disorder caused by acquired somatic mutations, physiologic effects of drugs, viruses, or environmental toxins that inhibit mitochondrial function" is also disclosed in the original application as filed. For support, see page 1, lines 17-18 of the application ("somatic mutations"), page 8, lines 13-14("drug-related side effects"), and original claim 14 ("pharmaceutical agents"). Thus, there is explicit and literal support for the limitation "a secondary disorder caused by acquired somatic mutations or physiologic effects of drugs." While the original specification does not contain specific language teaching that a

secondary disorder may be caused by physiologic effects of viruses or environmental toxins, such causation is clearly known in the art.

In addition, during the interview on January 6, 2009 with representative Victor Repkin, Esq., the Examiner raised the following point related to the alleged further deficiency of the written description. In particular, the Examiner stated that certain mitochondrial disorders recited in the Markush groups presented in independent claims are not true disorders or diseases but rather are symptoms through which "real" disorders manifest themselves. More specifically, the Examiner identified five such symptoms (i.e., mitochondrial renal tubular acidosis, lactic acidemia, hydroxyprolinuria, aminoaciduria, and 1+proteinuria) and required clarification.

In response, Applicants respectfully point out that in medical usage and practice it is quite usual to refer to the treatment of symptoms, as a kind of a short-hand expression, while in fact the underlying causes of the symptom are being treated. For instance, a doctor may say that she treats fever using aspirin, while of course she really uses aspirin to stop inflammation causing fever. Physicians having ordinary skill in the art have no difficulties understanding what is meant by such and similar expressions that are very common in the art.

However, being desirous of accelerating and facilitating the process of prosecuting the instant application, the independent claims at issue have been amended to delete reference to the symptoms associated with a mitochondrial disorder. Accordingly, what is now claimed is the treatment of a mitochondrial disorder followed by a Markush group relating to the disorders, i.e. multiple mitochondrial deletion syndrome, Leigh syndrome, 3-hydroxybutyric acidemia, pyruvate dehydrogenase deficiency, complex I deficiency, complex IV deficiency, and MARIAHS syndrome. It is submitted that when the independent and dependent claims are presented in such a form, there will be no questions regarding the sufficiency of the written description.

In view of the foregoing, it is respectfully submitted that the rejection of claims 67, 74-81, 84-91, 111, and 114-129 under 35 U.S.C. § 112, first paragraph, does not apply. Reconsideration and withdrawal of the rejection are respectfully requested.

C. Rejections Under 35 U.S.C. § 103(a)

Claims 67, 70, 73-81, and 84-91 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Nagley in view of Page et al., "Developmental Disorder Associated with Increased Cellular Nucleotidase Activity," *Proc. Natl. Acad. Sci. USA*, vol. 94, pp. 11601-11606 (1997) ("Page")(page 4, fourth paragraph of the Office Action). The rejection is respectfully traversed.

The Applicant's position remains that the *KSR* standard that has to be satisfied in order to make a valid rejection based on a *prima facie* case of obviousness has not in fact been satisfied as applied to these claims, as currently amended.

The Examiner's view remains that Nagley describes treatments directed to lactic acidosis and the therapy taking advantage of the mitochondrial effects of AZT. Combined with Page's teaching regarding the use of certain uridine dosing, the Examiner has concluded that there is an expectation of success for treating mitochondrial disorders using the teachings of Nagley. The Examiner has also stated that her broad reading is justified since claims 67, 91, and 95 recite the language "comprising."

Applicants disagree with the Examiner for bringing the teachings directed to multiple therapeutic agents into the process of interpreting the instant claims, and using this as a rationale in making the obviousness rejection. However, being desirous of facilitating the process of prosecution, the Applicants have amended claims 67, 91, and 95. Each of these claims now use the closed language "consisting of" when reciting the steps of the method. Thus, reading these claims as broadly as the Examiner did is impossible.

Accordingly, the teachings of Nagley describing the mitochondrial effects of AZT cannot be used because claims 67, 91, and 95, as amended, now exclude the use of the step of administering of AZT or any agents other than L or D isomer of a keto or an enol tautomer of Formula I, or IA. Therefore, the combination of Page and Nagley fails to satisfy one of the crucial requirements of *KSR*, i.e., it fails to teach or suggest all of the limitations recited in claims 67, 91, and 95, as amended.

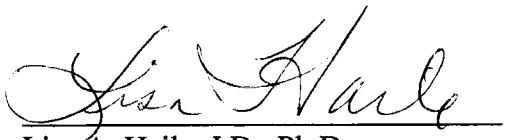
In view of the foregoing, it is respectfully submitted that each of claims 67, 91, and 95 is patentably distinguishable over Nagley in view of Page. Each of claims 70, 73-81, and 84-90 are directly or indirectly dependent on claim 67 and is, accordingly, considered patentable for at least the same reason. Withdrawal of the rejection and reconsideration are respectfully requested.

CONCLUSION

In view of the above amendments and remarks, reconsideration and favorable action on all claims are respectfully requested. In the event any matters remain to be resolved, the Examiner is requested to contact the undersigned at the telephone number given below so that a prompt disposition of this application can be achieved.

The Commissioner is hereby authorized to charge the amount of $960.00 as payment for the Three-Month Extension of Time fee ($555) and the Request for Continued Examination fee ($405) to Deposit Account No. 07-1896. No additional fees are believed to be due with the present communication, however, the Commissioner is hereby authorized to charge any fees that may be due in connection with the filing of this paper, or credit any overpayment to Deposit Account No. 07-1896, referencing the above-identified Attorney Docket Number.

Respectfully submitted,



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